

K061574

JUL 21 2006

**Summary of Safety and Effectiveness for  
COULTER® LH 750 Hematology Analyzer**

**1.0 General Information**

Device Generic Name(s): Automated differential cell counter

Device Trade Name(s): COULTER® LH 750 Hematology Analyzer

Device Classification: The COULTER® LH 750 Hematology Analyzer is a Class II medical device.

Applicant Name and Address: Beckman Coulter, Inc.  
Cellular Analysis Division  
11800 SW 147 Avenue  
Miami, FL 33196-2500

Date: June 6, 2006

**2.0 Legally Marketed Device(s)**

The modified COULTER® LH 750 Hematology Analyzer with claims substantial equivalence to the previously cleared COULTER® LH 750 Hematology Analyzer and COULTER® LH 750 Body Fluids Application.

FDA 510(k) Number(s): K011342 and K030606

**3.0 Device Description**

The product is an automated hematology analyzer capable of supplying a complete blood cell analysis and includes a differential leukocyte cell count. The product also provides automated reticulocyte analysis and enumeration of nucleated red blood cells (NRBCs) as well as an automated method for enumeration of RBCs and WBCs in body fluids. The following reagents, with 510(k) numbers indicated where applicable, are qualified for use on the COULTER LH 750 Hematology Analyzer with Software Version 2B (or higher):

- 5C Cell Control (K912133) and COULTER RETIC-C™ Cell control (K930119) hematology quality control materials used to monitor the instrument performance. COULTER® LIN-C® linearity control (K955334) verifies reportable range of the CBC parameters.
- COULTER® LH Series Diluent and ISOTON® 4 Diluent. Intended for use as a diluent for counting and sizing blood cells.
- COULTER Lyse S® III diff lytic reagent and COULTER Lyse S® 4 lytic reagent. Intended for the simultaneous quantitative determination of hemoglobin and for leukocyte counting and sizing.
- COULTER CLENZ® cleaning agent to prevent protein buildup on surfaces.
- COULTER Latron™ Primer and Latron Control (K885028) to monitor VCS performance.

- COULTER LH Series Pak, containing Erythrolyse™ lytic reagent and Stabilyse™ to preserve leukocytes in near-native state to allow differentiation into subpopulations.
- COULTER LH Series RETIC Pak for preparing samples for reticulocyte analysis.
- COULTER S-CAL® Hematology Calibrator (K840794), alternative to whole blood reference method of calibration. Intended for use in ensuring accurate instrument measurements.

#### **4.0 Principle of Method:**

The COULTER LH 750 Hematology Analyzer utilizes the Coulter Principle for enumerating and sizing blood cells, automatic diluting and mixing for sample processing and a single beam photometer for hemoglobinometry. It uses COULTER VCS (volume, conductivity, light scatter) technology for WBC Differential analysis and classification and reticulocyte analysis. The analyzer uses a reagent system consisting of an isotonic diluent, lytic reagents to lyse the red cells without significantly affecting the white cells and an instrument cleaner. Additionally, all systems include reagents used for reticulocyte staining and analysis.

For body fluids analysis, the specimen is aspirated into the LH 750 Analyzer via the manual mode and is diluted in separate WBC and RBC baths. The Coulter Method of counting cells is used to detect and measure changes in electrical resistance when a cell, suspended in a conductive diluent, passes through a small aperture. Each suspended cell acts as an insulator. As the cell passes through the aperture, it momentarily increases the resistance of the electrical path between two submerged electrodes, one located on each side of the aperture. The resistance generates an electrical pulse. The accumulation of electrical pulses are channelized, processed for coincidence correction, and multiplied by a calibration factor, yielding the WBC and RBC counts.

The WBC result represents the TNC (total nucleated cell count) in the analysis of Body Fluids.

#### **5.0 Indications for Use:**

The COULTER LH 750 Hematology Analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter For In Vitro Diagnostic Use in clinical laboratories. The COULTER® LH 750 Hematology Analyzer also provides automated reticulocyte analysis and nucleated red blood cell (NRBC) enumeration as well as an automated method for enumeration of RBCs and WBCs in body fluids.

#### **6.0 Description of the modification:**

The labeling for the marketed COULTER LH 750 hematology analyzer will be modified relative to the draft labeling submitted in the original Premarket notification (K011342) to reflect a revised MCV accuracy specification.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Nancy Nadler  
Staff Regulatory Affairs Specialist  
Beckman Coulter, Inc.  
11800 S.W. 147 Avenue  
M/S 31-B06  
Miami, Florida 33196-2500

JUL 21 2006

Re: k061574  
Trade/Device Name: COULTER® LH 750 Hematology Analyzer  
Regulation Number: 21 CFR § 864.5220  
Regulation Name: Automated differential cell counter  
Regulatory Class: II  
Product Code: GKZ  
Dated: June 6, 2006  
Received: June 7, 2006

Dear Ms. Nadler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

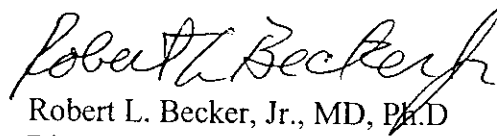
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,

A handwritten signature in cursive script, reading "Robert L. Becker, Jr.", written in dark ink.

Robert L. Becker, Jr., MD, Ph.D

Director

Division of Immunology and Hematology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

## INDICATIONS FOR USE

510(k) Number (if known): K061574

Device Name: COULTER® LH 750 Hematology Analyzer

### Indications For Use:

The COULTER LH 750 Hematology Analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter For In Vitro Diagnostic Use in clinical laboratories. The COULTER LH 750 Hematology Analyzer provides automated Reticulocyte analysis and enumeration of nucleated red blood cells (NRBCs) as well as an automated method for enumeration of RBCs and WBCs in body fluids.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use         
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Robert H. Beckman  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K061574